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| EXAMINER |
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HAMUD, FOZIA M

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| ART UNIT | PAPER NUMBER |
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1647

DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/763,293

Applicant(s)

LIDER ET AL

Examiner

Fozia M Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-12, 14 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-4, 7-8, 11-12, 14, 18-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### Detailed Office Action

1. Receipt of Applicants' amendment and arguments filed on 14 July 2003 in Paper No.14 is acknowledged. Claims 1-2, 13, 15-17 have been canceled, claims 3, 7, 11, 18 have been amended, and new claims 19-20 have been added. (Claim 4 is amended and it is also indicated as being canceled, which is confusing. Claim 4 will be treated as amended). Thus claims 3-12, 14, 18-21 are pending, of which claims 3-4, 7-8, 11-12, 14 and 18 are under consideration. Claims 5, 6, 9-10 stand withdrawn from consideration as they are drawn to non-elected species.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No.14, 07/17/03:

(I) Applicant's arguments with respect to claims 1-4, 7-8, 11-12, 14 and 18, have been considered but are moot in view of the new ground(s) of rejections.

#### ***Claim Rejections under 35 U.S.C. §112:***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 3-4, 11, 12, 14, 18-21 stand rejected under 35 U.S.C. 112, first paragraph for reasons of record set forth in the office action mailed on 14 January 2003, in Paper NO:13, pages.

Applicants argue that claim 8 specifically recites and exemplifies derivatives of pep2 of SEQ ID NO:1, where pep15 to pep35 have been shown to have anti-inflammatory activity. Thus, Applicants contend that by reciting that the claimed

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synthetic peptide must be functions, and in view of the teachings in the specification of the type of deletion, addition, and substitution and location of the modification to pep2 as exemplified, the scope of the claimed invention is fully enabled.

This argument is fully considered but is found persuasive in part. Instant specification discloses that pep15-pep35, (where in specific modifications are made to pep2), have anti-inflammatory activities as measured by the inhibition of IL-8 secretion. Thus instant specification is enabling for a synthetic peptides having the core structure of pep2, and having the modifications recited in claims 7 and 8, but is not enabling for "all" synthetic peptides of IL-2 having the activities recited in claim 3.

With respect to claims 3, 11-12, 14 and 18, Applicants are arguing limitations not recited in the claims, because these claims are not limited to the peptides derived from pep2, but are drawn to "all" possible peptides that are derived from IL-2 which display the recited activities. Instant specification discloses that pep2 (SEQ ID NO:1), which is amino acid residues 136-143 of IL-2, (page 6, line 16), displays inhibitory effects on IL-2 induced adhesion of T cells to fibronectin, collagen IV or laminin, inhibits T cell chemotactic migration induced by IL-2 or MIP-1, inhibits spontaneous or TNF- induced IL-8 or IL-1 and that it tolerates specific modifications, without causing major changes to these activities. However, since instant claims 3, 14 and 18 are drawn to "all" possible IL-2 derived peptides, these claims are not commensurate in scope with what is enabled. Furthermore, the state of the art is such that it is unpredictable the "all" possible fragments of IL-2 would have the desired activities. Applicants have shown that specific fragments of IL-2 have anti-inhibitory effect on some IL-2 induced

processes, however, one of ordinary skill in the art would not extrapolate this the "all" possible fragments would also have all the desired activities.

Therefore, instant specification is enabling for a synthetic peptide pep2, (SEQ ID NO:1) having the specific modifications recited in claims 7 and 8, and displaying the activities recited in claim 3, but does not enable "all" possible IL-2 derived synthetic peptides having the activities recited in claim 3.

Claims 12, 14, 18-21 are rejected under 35 U.S.C. 112, first paragraph, in so far as they depend on claims 3, 4 and 11 for the limitations set forth directly above.

**Claim rejections-35 U.S.C. § 112, second paragraph:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 4, 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Regarding claim 4, the recitation of non-elected peptides renders the claim indefinite. Appropriate correction is required.

4b. Claim 4(vi), is vague and indefinite for reciting ".....chemical derivative" of the peptides i-v, because there is unclear how to chemically derive these derivatives or what is the chemical to be used to derive these peptides.

4c. Claim 4(ix), is vague and indefinite for reciting ".....a number of the same or different peptides i to viii", because it is unclear what different peptides besides the ones recited in sub-parts i-viii that are supposed to be part of this multimer. Furthermore, the

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claim does not set the number of different or same peptides that make up the claimed multimer. The metes and bounds of the claim can not be ascertained.

4d. Regarding claim 7 the phrases "preferably" recited in numerous places, and "such as" recited in 7(e), render the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

4e. Claim 7 (e), recites the limitation "the important", however, there is insufficient antecedent basis for this limitation in the claim. Furthermore, it unclear why Asn residue is more important than the other amino acid residues the make up pep2.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, in so far as it depends on claim 7 for the limitations set forth directly above.

***Conclusion:***

5. No claims is allowed.

Claims 7-8, 19-21 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, set forth in this Office action.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory Information:***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
09 October 2003

*Prema Mertz*  
**PREMA MERTZ**  
**PRIMARY EXAMINER**